

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION) MDL 2804
OPIATE LITIGATION)
) Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:)
) Judge Dan Aaron Polster
Track Three Cases)
) OPINION AND ORDER GRANTING IN
) PART DEFENDANTS' MOTION TO
) EXCLUDE OPINIONS OF JAMES
) RAFALSKI

Before the Court is Defendants' Motion to Exclude the Opinions Offered by James Rafalski.¹ Plaintiffs (Ohio's Lake and Trumbull Counties) filed a response, and Defendants filed a reply. For the reasons stated below, the Motion is **GRANTED IN PART**.

Rafalski, a former Drug Enforcement Administration ("DEA") Investigator, presents opinions in these *Track Three* cases about, *inter alia*, the effectiveness of the Pharmacy Defendants' efforts at the distribution level to prevent the diversion of controlled substances into illegitimate channels. Specifically, Rafalski identified seven threshold methods that Defendants could use to identify potentially suspicious orders from their retail chain pharmacies.² In turn,

¹ The motion to exclude Rafalski was filed by: (1) Giant Eagle, Inc. and HBC Service Company (collectively, "Giant Eagle"); (2) Walmart Inc.; and (3) Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Support Center, and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center (collectively, "Rite Aid"). Rite Aid has since been severed from these proceedings. *See* Order docketed on 08/26/21 (Doc.#: 3894)). The remaining *Track Three* Defendants (CVS and Walgreens) did not join in the motion.

² The seven methods are: (1) Maximum Monthly, Trailing Six-Month Pharmacy Specific Threshold; (2) Trailing Six-Month Maximum Monthly, Fixed After First Triggered Threshold; (3) Twice Trailing Twelve-Month Average; (4) Three Times Trailing Twelve-Month Average; (5) Maximum 8,000 Dosage Units Monthly; (6) Maximum Daily Dosage Units; and (7) Maximum Monthly Trailing Six-Month Specific Threshold on Rolling 30 Days. *See* Rafalski T3 Rpt. at 45-56.

Craig McCann, a data expert, applied these threshold criteria to the DEA's Automation of Reports and Consolidation Orders System ("ARCOS") data and Defendants' transactional data to identify transactions that meet the specified criteria of each method. Together with McCann's calculations, Rafalski provides opinions, as to specific Pharmacy Defendants, regarding the number of orders placed by pharmacies in the *Track Three* Counties that each threshold method would have flagged as potentially suspicious. *See* Rafalski T3 Rpt. at 45-56. Additionally, Rafalski expresses opinions regarding alleged deficiencies in Defendants' suspicious order monitoring systems (SOMS) and due diligence efforts. *Id.* at 57-158.

In *Track One*, the Court ruled, *inter alia*, that Rafalski could not express legal opinions as to what the law requires, or whether Defendants' conduct violated the law. *See Rafalski T1 Daubert Order, In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934490, at *3-5 (N.D. Ohio Aug. 20, 2019) (Doc. #: 2494 at 6-10). As to his remaining opinions, the Court found that Rafalski, based on his extensive experience as a DEA Investigator, has reliable expertise to identify methods available to flag potentially suspicious orders.³ *See id.* at *4-7 (Doc. #: 2494 at 8-15). Further, the Court found "Rafalski clearly has experience and expertise regarding the components and characteristics he would expect to be included in an effective SOMS and due diligence program," and "it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged." *Id.* at *4, *6 (Doc. #: 2494 at 8, 12).

³ As a DEA Investigator for 13 years (from 2004 to 2017), Rafalski conducted investigations of DEA registrants, including regulatory investigations involving Distributors' compliance with DEA requirements regarding SOMS. For more information on Rafalski's credentials and experience, see Rafalski T3 Rpt. at 4-7 and *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 3934490, at *1 (Doc. #: 2494 at 2-4).

In *Track Three*, Defendants ask the Court to apply its *Track One* ruling and again preclude Rafalski from expressing opinions on ultimate legal issues. Defendants also assert that: (1) “new” evidence demonstrates Rafalski’s SOMS and due diligence opinions are unreliable; and (2) Rafalski’s causation opinions are unreliable and unhelpful. The Court agrees again with Defendants that Rafalski may not opine on ultimate legal issues, and also that his ultimate causation opinions must be excluded. After examining the evidence cited by Defendants, however, the Court reaffirms its *Track One* ruling that Rafalski’s SOMS and due diligence opinions are reliable and admissible. The Court’s reasoning is set forth below.

I. Legal Standards.

The Court incorporates by reference the applicable *Daubert* legal standards set forth in its *Track One Order Denying Motion to Exclude Rosenthal* (Doc. #: 2495 at 1-10).⁴

II. Rafalski’s Opinions.

In his *Track Three* Report, Rafalski summarizes his opinions as follows:

1. The Controlled Substance Act (CSA) is designed to provide for a closed delivery system related to the pharmaceutical supply chain. The CSA requires DEA registration for each member of the closed supply chain, known as a registrant. This is due to the dangerous and abusive nature of the controlled substances that flow through the pharmaceutical supply chain.
2. As a member of the closed delivery system each registrant takes on certain statutory and regulatory obligations to ensure the safety and efficiency of the pharmaceutical supply chain. These statutory and regulatory duties have remained the same sense [sic] the enactment of the CSA.
3. The pharmaceutical supply chain flows from manufacturer (labeler) to wholesale distributor and then to the end dispenser (pharmacy, hospital, practitioner). This gives the distributors a unique position in the supply chain in

⁴ *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3934597, at *1-5 (N.D. Ohio Aug. 20, 2019).

that they are the last checkpoint before the controlled substances go to the end dispenser.

4. Under the CSA and the implementing regulations the distributors have two significant obligations that are designed to ensure that these controlled substances do not veer outside of the closed supply chain. These statutory and regulatory obligations come from:
 - 21 U.S.C.A. § 823(b)(1); which requires the “maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”
 - 21 C.F.R. § 1301.74(b); which require[s] the registrant to “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” Then the registrant is required to notify the DEA of all identified suspicious orders prior to shipment.
5. Each of these obligations play a vital role in protecting the integrity of the pharmaceutical supply chain. It is up to each registrant to design a system, often referred to as a suspicious order monitoring system (SOMS), that will comply with these regulatory requirements based on the differing type of business models they choose as customers. For example, a wholesale distributor that only services hospitals would need a SOMS different from that for one who services veterinary clinics.
6. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop and implement a SOMS that would ensure the maintenance of effective controls against diversion. While each of them had different systems [that they implemented,] each of these systems were either faulty in their design or in the manner they were operated.
7. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop a comprehensive system to monitor, detect, and report all suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties. This failure is exacerbated as there were significant timeframes when the Defendants would identify suspicious orders and still ship the orders to the respective pharmacies.
8. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to conduct adequate due diligence on suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties, to determine whether the customer was engaged in diversion;
9. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each distributed opioids to pharmacies in [] Lake and Trumbull Counties in disproportionately

excessive amounts without adequately documenting [the] justification [for those amounts]; and

10. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to halt suspicious shipments of opioid orders to pharmacies in Lake and Trumbull Counties they knew, or should have known, were going to be diverted.

Rafalski T3 Rpt. at 8-9 (emphasis added).⁵

Additionally, in other parts of his *Track Three* Report, Rafalski states “causation” opinions:

I am further of the opinion that this systematic failure [to maintain effective controls against diversion] was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County.

and

It is further my opinion that this misconduct⁶ [*i.e.*, Defendants’ inadequate due diligence and failure to respond to indicators of suspicious orders] led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.

Rafalski T3 Rpt. at 7, 57.⁷

⁵ Rafalski’s *Track Three* opinions are substantially similar those he expressed in *Track One*. Compare Rafalski T3 Rpt. at 7, 40-158, with Rafalski T1 Rpt. at 7, 36-144 (Doc. #: 1999-21).

⁶ Rafalski describes this “misconduct” as: “Defendants’ failures to comply with requirements of the Controlled Substances Act.” Rafalski T3 Rpt. at 57. For reasons stated below, Rafalski may not opine on whether Defendants’ conduct constituted “misconduct” or otherwise violated the law. However, Rafalski may testify as to why, in his opinion, Defendants’ SOMS and due diligence measures were inadequate or ineffective in preventing diversion.

⁷ Rafalski expressed similar “causation” opinions in his *Track One* Report. See Rafalski T1 Report at 7, 46 (Doc. #: 1999-21) (“I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Cuahoga County and Summit County.”) (“It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT1 jurisdictions.”). In *Track One*, Defendants did not specifically challenge these “causation” opinions. See Defs. T1 Rafalski Mem. at 12-15 (Doc. #: 1900-1). The *Track One* Defendants *did* raise concerns over Rafalski’s deposition testimony opining that, if an order is identified as suspicious, it would likely be diverted. See *id.* However, *Track One* Plaintiffs conceded Rafalski did not include such a statement in his Report (and did not intend to so testify at trial), so the Court did not address any of Rafalski’s *Track One* “causation” opinions. *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 3934490, at *7 (Doc. #: 2494 at 14).

III. Analysis.

Defendants seek to exclude Rafalski's *Track Three* opinions on three grounds. First, Defendants ask the Court to apply its *Track One* ruling and preclude Rafalski from offering opinions on ultimate legal issues. Second, Defendants assert "new" evidence shows Rafalski's SOMS and due diligence opinions are unreliable. Third, Defendants argue Rafalski's causation opinions are unreliable and unhelpful. The Court addresses each argument below.

A. Legal Opinions.

Defendants ask the Court to apply its *Track One* holding and preclude Rafalski from expressing legal opinions or ultimate conclusions of law. Motion at 2, 8.⁸ In *Track One*, the Court found that, while Rafalski "may refer to the law as instructed by this Court" and "express opinions as to particular characteristics in SOMS and due diligence procedures that he finds are effective in preventing diversion," he may not opine on what the law requires or whether Defendants' conduct violated the law. *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 3934490, at *4-5 (Doc. #: 2494 at 8-10).⁹

Plaintiffs respond that Rafalski's *Track Three* opinions are not "the kind of legal conclusions this Court found impermissible in *Track One*." Response at 9 (emphasis added). Rather, Plaintiffs assert, Rafalski's opinions fall within the permissible scope outlined by the Court

⁸ Citations to Defendants' "motion" in this opinion are to their memorandum in support.

⁹ In *Track One*, the Court sustained Defendants' motion to exclude four specific opinions on grounds that: (1) Rafalski had refused to disclose the basis for them; and (2) they constituted impermissible legal conclusions. See *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 3934490, at *3-5 (Doc. #: 2494 at 6-10). The specific opinions were: (1) the law required Defendants to halt all shipments after identifying an initial suspicious order; (2) DEA regulations require certain "key components" regarding SOMS and due diligence systems; (3) the Controlled Substance Act ("CSA") and its implementing regulations require Manufacturers to consider prescription and chargeback data; and (4) DEA registrants must document and permanently retain suspicious order reports and due diligence records. See *id.* These opinions do not appear in Rafalski's *Track Three* Report.

in *Track One*. More specifically, Plaintiffs contend Rafalski's opinions center on what, in his experience, constitutes effective controls against diversion, and whether Defendants put systems with such controls into place. *Id.*

Rafalski may certainly quote relevant statutes and regulations, and may offer opinions regarding whether, in his experience, a SOMS is effective if it has or does not have certain characteristics. But Rafalski goes well beyond that to offer many legal opinions and ultimate legal conclusions in his Report. *See, e.g., id.* at 57 (Defendants' inadequate due diligence constitutes a failure to comply with CSA requirements); 69-71 (CVS failed to maintain effective control in violation of 21 U.S.C. § 823(b)(1)); 88 (Walgreens failed to design and operate a SOMS in violation of 21 C.F.R. § 1301.74(b)); 97 (cutting orders without reporting them to the DEA as suspicious fails to comply with Walgreens CSA obligations); 115, 117 (Rite Aid failed to maintain effective controls in violation of 21 U.S.C. § 823(b)(1) and failed to design and operate a SOMS in violation of 21 C.F.R. § 1301.74(b)); 131, 135 (same for Walmart); 149, 153 (same for Giant Eagle).

That said, Defendants have not identified the *specific* "legal opinions" they seek to exclude. Some of Rafalski's legal statements will accurately reflect "the law as instructed by this Court," and the plain language of the statutes and regulations, which he may permissibly refer to, especially to provide background and context for his SOMS and due diligence opinions. *Rafalski Tl Daubert Order, In re Opiate*, 2019 WL 3934490, at *4 (Doc. #: 2494 at 8). At this juncture, the Court declines to sift through his entire 158-page Report to identify which opinions are impermissible. Nevertheless, in the context of trial, as to Rafalski and all expert witnesses, the Court will impose well-established legal principles generally prohibiting experts from opining as to what the law requires, or whether Defendants' conduct violated the law. *See id.* at *4 (Doc. #: 2494 at 7-8);

Berry v. City of Detroit, 25 F.3d 1342, 1353-54 (6th Cir. 1994) (an expert may not opine as to legal conclusions or the ultimate question of liability). The Court therefore sustains Defendants' motion on this ground and will preclude testimony by Rafalski as to impermissible legal opinions or ultimate conclusions of law. The Court warns Defendants, however, that this ruling could change at trial if their questioning clearly "opens the door" to such opinions.

B. Reliability of SOMS and Due Diligence Opinions.

In *Track One*, the Court found Rafalski's extensive field experience as a DEA Investigator provides reliable expertise for his opinions on whether particular characteristics of SOMS and due diligence procedures are effective in preventing diversion. *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 3934490, at *4-5 (Doc. #: 2494 at 8-10). Defendants urge the Court to now depart from this ruling, arguing "new" evidence shows Rafalski's SOMS and due diligence opinions are inherently unreliable. This "new" evidence primarily consists of (1) Rafalski's deposition testimony; and (2) DEA Reports for on-site investigations of Giant Eagle, which Defendants contend show that, in evaluating the effectiveness of their SOMS and due diligence procedures, Rafalski did not utilize the same methods he and other agents used in performing DEA field investigations. *See Motion at 9-12.*

Essentially, Defendants argue Rafalski's SOMS opinions cannot possibly be reliable unless he followed the exact same methods and procedures as he would in conducting a DEA field investigation. *See id.* at 3, 11. This argument ignores the substance and purpose of Rafalski's testimony. Rafalski does not purport to offer opinions about what a current DEA field investigation of Defendants' facilities would reveal. Rather, utilizing specialized knowledge gained from his experience as a DEA Investigator, Rafalski reviewed evidence produced in the

litigation (which goes well beyond what a normal DEA investigation would reveal) and formed opinions regarding the effectiveness of Defendants' SOMS and due diligence efforts in past years. In fact, it is precisely Rafalski's specialized knowledge and DEA experience that form the basis for the reliability of his opinions.

In determining whether an expert's reasoning or methodology is reliable, a trial judge exercises broad latitude to determine what specific factors are a reasonable measure of reliability in a specific case. *First Tenn. Bank Nat'l Ass'n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (*Daubert's* list of specific factors is non-exhaustive and does not necessarily apply to every expert or in every case); *see also Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 430 (6th Cir. 2007) (the trial court's gatekeeping inquiry is "very flexible" and "must be tied to the facts of a particular case, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony") (citations omitted). Particularly with respect to non-scientific experts, like Rafalski, "the relevant reliability concerns may focus upon personal knowledge or experience." *First Tenn. Bank*, 268 F.3d at 335 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)).

Indeed, when assessing the reliability of non-scientific experts, courts have found that a reliable methodology may include observing relevant evidence and applying specialized knowledge gained from the expert's educational and practical experience. *See Wood v. Wal-Mart Stores East, LP*, 576 F. App'x 470, 472 (6th Cir. 2014) (affirming the trial court's admission of expert testimony by "a non-scientific witness whose expertise came primarily from personal knowledge and experience"); *Harris v. Goins*, No. 6:15-151-DCR, 2017 WL 4080692, at *3 (E.D. Ky. 2017) (allowing expert testimony by a law enforcement officer). This is precisely the type of

reliable methodology that Rafalski applies here.¹⁰ As in *Track One*, the Court finds Rafalski's extensive experience as a DEA Investigator provides a reliable basis for his opinions regarding the historical effectiveness *vel non* of Defendants' SOMS and due diligence procedures.

Defendants assert Rafalski should have physically inspected their pharmacies and evaluated whether diversion actually occurred there, and cannot now testify without having done so. Rafalski's opinions, however, focus on Defendants' SOMS and due diligence procedures at the *distribution* level. Whether diversion occurred at the *dispensing* level is a separate inquiry upon which Rafalski does not offer an opinion.¹¹ Of course, Plaintiffs may present evidence of dispensing-level diversion by other means.

Defendants also contend Rafalski should have examined and given weight to DEA inspection reports showing they were in "full" compliance with DEA security regulations. These reports, however, do not conclusively establish Defendants met all of their SOMS and due diligence obligations.¹² Rather, Rafalski testified he did not place a "high value" on DEA

¹⁰ Defendants argue Plaintiffs must show "objective proof" supporting the reliability of Rafalski's opinions. Motion at 3, 11 (citing *Johnson*, 484 F.3d at 435). The Court does not disagree. However, Defendants go further and say this "objective proof" standard *requires* Plaintiffs to show: (1) Rafalski used the exact same methods as if he were conducting a DEA field investigation; and/or (2) diversion actually occurred at Defendants' pharmacies. Motion at 3, 9-11. Here, Defendants overlook the fact that "objective proof" of reliability can be based on an expert's specialized knowledge and experience.

¹¹ In deposition, Rafalski testified he did not look at diversion factors for Defendants' pharmacies. Rafalski Depo. at 123:11 to 124:16, Defs. Ex. 2. Similarly, with respect to whether he reviewed the testimony of Ohio Board of Pharmacy ("OBOP") agents who inspected Defendants' pharmacies in Lake and Trumbull Counties, Rafalski testified: "My experience in dealings with boards of pharmacies and the types of inspections they conduct are more at the pharmacy level and typically don't look at the same type of issues that I look at." Rafalski Depo. at 159:5-9.

¹² In support of their motion, Defendants submit three DEA Investigation Reports for one of the Moving Defendants, *i.e.* Giant Eagle. Defs. Ex. 3. But these Reports indicate the investigators gave varying levels of attention to SOMS and due diligence measures: the 2011 Report does not mention SOMS or due diligence; the 2013 Report states the investigator informed Giant Eagle of its SOMS and due diligence responsibilities and advised management to develop a better system of due diligence; and the 2017 Report contains a two-page summary of Giant Eagle's SOMS and due diligence efforts. *Id.* Defendants may seek to counter the weight of Rafalski's testimony by adducing evidence of DEA investigative reports that gave pharmacies a "passing grade," but these reports do not show Rafalski's methodology is unreliable. See *T3 SJ Order re Giant Eagle, In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2021 WL 3917174, at *1-2 (N.D. Ohio Sept. 1, 2021) (Doc. #: 3913 at 2-4) (Plaintiffs' evidence indicates the

inspection reports because, in his experience, there were times generally when a registrant had clean inspection reports, yet he still took action against them (presumably for noncompliance). Rafalski Depo. at 455:4-17. Whether the DEA's actual investigation results diminish the weight of Rafalski's testimony is a matter for the factfinder.

Finally, Defendants assert Rafalski has not explained why, as an expert, he found 100% of the SOMS he examined to be noncompliant, whereas, as a DEA Investigator, he found only 50% to be noncompliant. *See* Motion at 9-10. Again, this is a quintessential credibility question that goes to the weight of Rafalski's testimony, not its admissibility. *See Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

For these reasons, the Court denies Defendants' motion to exclude Rafalski's SOMS and due diligence opinions.

C. Causation Opinions

As noted, Rafalski's *Track Three* Report contains two "causation" opinions: (1) Defendants' failure to maintain effective controls "was a substantial cause of the opioid epidemic ... in Lake County and Trumbull County;" and (2) Defendants' inadequate due diligence and failure to respond to indicators of suspicious orders "led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions." Defendants assert these opinions are unreliable and unhelpful because: (1) they are based on an unreliable methodology to identify suspicious orders; and

DEA investigations were quite limited in scope, in that the investigators were merely looking at whether Giant Eagle had a SOMS and did not analyze whether the SOMS was effectively implemented).

(2) Rafalski has not provided an appropriate analysis or other support for his causation opinions, and they constitute impermissible legal conclusions. *See* Motion at 12-14; Reply at 9-13.

1. Reliability of Underlying Methods to Identify Suspicious Orders

For reasons previously discussed, the Court rejects Defendants’ argument that Rafalski’s underlying methods to identify potentially suspicious orders is unreliable. Defendants’ briefing adds nothing new to alter the Court’s ruling on this issue. *See* Motion at 13.

That Defendants were not *required* to use any of the seven threshold formulas offered by Rafalski, or that the formulas give greatly varying results when applied to Defendants’ transactional data, does not diminish their illustrative value in identifying the various methods that Defendants *could have employed* to monitor suspicious orders.¹³ *See* Response at 15-16. Further, that Rafalski did not analyze whether any of the “suspicious” orders were in fact diverted at the *dispensing* level does not impact the reliability of his opinions that those orders were “suspicious” at the *distribution* level.

As in *Track One*, the Court finds “Rafalski’s methodologies are reliable and would aid the jury’s determination of material issues in the case.” *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 39334490, at *6 (Doc. #: 2494 at 12).

2. Insufficient Analysis or Support and Ultimate Legal Conclusions.

¹³ Rafalski was not required to test the various threshold results to determine if, in fact, they flagged orders that were actually suspicious. *Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 39334490, at *6 (Doc. #: 2494 at 12).

Defendants assert Rafalski has not engaged in a sufficient causation analysis or otherwise provided adequate support for his causation opinions.¹⁴ Further, Defendants assert the opinions constitute impermissible legal conclusions.

a. Causation Opinion #1: Defendants’ failure to maintain effective controls was a “substantial cause” of the opioid epidemic.

As to the first causation opinion, *i.e.* that Defendants’ failure to maintain effective controls was a “substantial cause” of the opioid epidemic, the Court agrees this opinion impermissibly embraces an ultimate legal issue that is for the jury’s determination. *See, e.g., Berry*, 25 F.3d at 1353 (an expert may not draw a legal conclusion; rather, an expert may only state an opinion “that suggests the answer to the ultimate issue or that gives the jury all the information from which it can draw inferences as to the ultimate issue”); *Torres v. County of Oakland*, 758 F.2d 147, 150-51 (6th Cir. 1985) (an expert’s opinion must stop short of embracing the “legal terminology” that frames the ultimate legal conclusion which the jury must reach in the case). In other words, this “causation” opinion does little more than impermissibly tell the jury what result to reach, which runs the risk of interfering with the Court’s jury instructions and would not be helpful to the jury.¹⁵ *See Woods v. Lecureux*, 110 F.3d 1215, 1120-21 (6th Cir. 1997); *see also* Fed. R. Evid. 704, Advisory Committee Notes (testimony that offers nothing more than a legal conclusion, *i.e.* does little more than tell the jury what result to reach, is properly excluded).

Moreover, Rafalski admits he has not performed any type of analysis to determine the amount of diversion that actually occurred at Defendants’ pharmacies, nor how that calculation

¹⁴ Defendants do not challenge Rafalski’s qualifications to express “causation” opinions. *See* Motion at 12-15; Reply at 9-13.

¹⁵ Plaintiffs assert Rafalski’s causation opinion is supported by this Court’s *Track One* summary judgment ruling on the issue of causation. There, the Court found that, given the massive increases in the supply of prescription opioids into the subject counties, combined with evidence suggesting a complete failure by distributors and pharmacies to maintain effective controls against diversion, “a factfinder could reasonably infer these failures were a substantial contributing factor in producing the alleged harm suffered by Plaintiffs.” Response at 17 (quoting *T1 SJ Order on*

would compare vis-à-vis the many other factors – such as bad doctors, pill mills, other independent pharmacies, and allegedly misleading marketing by manufacturers – that may also have contributed to causing the opioid epidemic. Without this information, the Court cannot find Rafalski’s causation opinion is based on sufficient facts or data or the product of reliable principles and methods.¹⁶ See, e.g., *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 252-53 (6th Cir. 2001) (plaintiffs failed to provide a valid scientific basis for an expert’s causation opinion regarding physical injuries allegedly caused by PCBs where, *inter alia*, the expert failed to account for a number of other possible causes or confounding factors).

Accordingly, the Court sustains Defendants’ motion on this ground and will exclude Rafalski’s opinion that Defendants’ SOMS failures were a “substantial cause” of the opioid epidemic.¹⁷

b. Causation Opinion #2: Defendants’ due diligence failures “led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.”

Rafalski’s second causation opinion, *i.e.* that Defendants’ due diligence failures “led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions,” does not embrace an impermissible ultimate legal conclusion. Nevertheless, Rafalski has failed to provide a sufficient analysis or otherwise shown a reliable basis to support this opinion.

Causation, In re Nat’l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 4178617, at *3 (N.D. Ohio Sept. 3, 2019) (Doc. #: 2561 at 9)). That a factfinder may reasonably draw such an inference, however, does not mean Rafalski can offer that opinion.

¹⁶ The Court observes, however, that unless the opioids constituting the suspicious orders were merely stockpiled at and never dispensed from the pharmacies to which they were shipped, another expert may permissibly infer those suspicious opioids were eventually dispensed and diverted.

¹⁷ In light of this ruling, the Court does not specifically address Defendants’ remaining arguments as to this causation opinion. The Court nevertheless notes that the analysis below (with respect to the second causation opinion) applies equally to the first causation opinion.

As discussed, Rafalski expresses reliable opinions regarding: (1) Defendants' alleged failure to maintain effective controls and conduct adequate due diligence to prevent diversion; (2) seven threshold methods that Defendants could have used to flag potentially suspicious orders; and (3) the number of orders that each method would have flagged as suspicious. Further, Rafalski opines that ARCOS data and/or Defendants' transactional data (as depicted in graphs prepared by data expert Craig McCann) show a clear escalation of prescription opioids *distributed* by Defendants into the *Track Three* Counties without conducting sufficient due diligence, which indicates a failure to maintain effective control. Rafalski T3 Rpt. at 69-71 (CVS), 84-87 (Walgreens), 115-116 (Rite Aid), 132-135 (Walmart), and 149-152 (Giant Eagle). Further, Rafalski opines that Defendants' SOMS and due diligence failures "directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances." *Id.* at 45.

These opinions reliably support an inference that, at the *distribution* level, Defendants shipped mass quantities of suspicious orders to their pharmacies in the *Track Three* Counties without performing adequate SOMS and due diligence procedures to protect against diversion. However, to conclude pills from those orders actually ended up being diverted into improper channels in the *Track Three* Counties, one must also find that diversion occurred at the *dispensing* level, *i.e.* that Defendants' pharmacies, in fact, used the "suspicious" orders they received to dispense an "excess quantity of opiate pills" through the filling of illegitimate opioid prescriptions.

Rafalski's Report contains no analysis or other foundational evidence to reasonably support an inference that diversion occurred at the *dispensing* level. In other words, Rafalski's Report lacks any reference to foundational facts or other evidence to support his conclusion that Defendants' pharmacies actually diverted opiate pills into the illicit market in the *Track Three*

Counties and, if so, the quantity of any pills so diverted. Moreover, Rafalski provides no explanation or analysis to support his conclusion that, assuming diversion in fact occurred at the *dispensing* level, it was caused by Defendants' SOMS and due diligence failures at the *distribution* level. Instead, Rafalski merely makes impermissible "speculative jumps" that Defendants' alleged SOMS failures at the distribution level must have resulted in diversion at the dispensing level. In so doing, Rafalski fails to provide a sufficient foundation for this second causation opinion. *See Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671-72 (6th Cir. 2010) (expert's opinion that manganese exposure caused plaintiff's condition lacked sufficient foundation where the expert failed to explain how he made "leaps" in the causal chain).

In sum, on this record, Plaintiffs have not shown that Rafalski's second causation opinion is based on sufficient facts or data or is the product of reliable principles and methods, or that Rafalski has reliably applied any such principles and methods to the facts of the case.¹⁸ *See, e.g., In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008); Fed. R. Evid. 702; *see also Sardis v. Overhead Door Corp.*, ___ F.3d ___, 2021 WL 3699753, at *6 (4th Cir. Aug. 20, 2021) ("to the extent an expert makes inferences based on the facts presented to him, the court must ensure that those inferences were 'derived using scientific or other valid methods'") (citation omitted).

The Court therefore sustains Defendants' motion on this ground and will exclude Rafalski's opinion that Defendants' due diligence failures "led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions."

¹⁸ The Court notes Plaintiffs have not asserted that Rafalski's experience as a DEA Investigator provides him with specialized knowledge or expertise to determine the causal effect of SOMS failures on actual diversion.

IV. Conclusion.

For the foregoing reasons, Defendants’ Motion to Exclude the Opinions Offered by James Rafalski is **GRANTED IN PART**. The Court hereby reaffirms its *Track One* ruling that Rafalski may not opine on what the law requires or whether Defendants’ conduct violated the law. Further, Rafalski may not express “causation” opinions that: (1) Defendants’ failure to maintain effective controls “was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County;” and (2) Defendants’ inadequate due diligence and failure to respond to indicators of suspicious orders “led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.”

Defendants’ Motion to Exclude the Opinions Offered by James Rafalski is otherwise **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster September 7, 2021
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE